# APPENDIX A. 510(k) SUMMARY

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| Sponsor/Submitter: | Abbott Laboratories (Perclose, Inc.)<br>Abbott Vascular Devices<br>400 Saginaw Drive<br>Redwood City, CA 94063 |
| Contact Person: | Joanna Kuskowski<br>Regulatory Affairs Coordinator<br>Phone:(650) 474-3331<br>Fax:(650) 474-3020 |
| Date of Submission: | April 9, 2004 |
| Device Trade Name: | Fox Plus PTA Catheter |
| Device Classification: | Class II |
| Regulation Number: | 21 CFR 870.1250 |
| Classification Name: | Percutaneous Transluminal Angioplasty Catheter |
| Product Code: | LIT |
| Predicate Device: | Fox PTA Catheter (K020854) |
| Intended Use: | The Fox Plus PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae. This catheter is not intended for the expansion or delivery of stents. |
| Device Description: | The Fox Plus PTA Catheter is a standard over-the-wire PTA catheter. The double lumen catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the second lumen allows access to the distal tip of the catheter for guidewire insertion (max 0.035"). The balloon material expands to a known diameter at specific pressure. |
| Summary of Substantial Equivalence: | The Fox Plus PTA Catheter is substantially equivalent to the predicate device. Substantial equivalence was confirmed through non-clinical testing. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2004

Abbott Laboratories, Inc.
c/o Ms. Joanna Kuskowski
Abbott Vascular Devices (Perclose, Inc.)
800 Saginaw Drive
Redwood City, CA 94063

Re: K040954
Fox Plus PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Angioplasty, Peripheral, Transluminal
Regulatory Class: Class II (two)
Product Code: LIT
Dated: April 9, 2004
Received: April 13, 2004

Dear Ms. Kuskowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Appendix B. Indications for Use

510(k) Number (if known): K040954

Device Name: Fox Plus PTA Catheter

Indications For Use: The Fox Plus PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

This catheter is not intended for the expansion or delivery of stents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniak

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040954